



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,457	02/10/2004	Eitan Konstantino	021770-000600US	3495
20350	7590	07/12/2006		
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER NEAL, TIMOTHY J	
			ART UNIT 3731	PAPER NUMBER

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/776,457

Applicant(s)

KONSTANTINO ET AL.

Examiner

Timothy J. Neal

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 21-53 and 56-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>see next page</u> . | 6) <input type="checkbox"/> Other: _____ |

Information Disclosure Statements Mail Dates: 3/28/2005, 11/19/2004, 5/21/2004

TJN

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hijlkema (U.S. 5,792,415).

Regarding **claim 1**, Hijlkema discloses a catheter body having a proximal end and a distal end (Fig. 1 Item 2); and a radially expansible balloon near the distal end of the catheter body (Fig. 1 Item 9), the balloon comprising a proximal end, a distal end, and at least one permanent fold line formed on the balloon prior to folding, the fold line extending helically along at least a portion of the surface of the balloon (Fig. 4 Item 22).

Regarding **claim 3**, Hijlkema discloses each fold line is parallel to each other (Fig. 6).

Regarding **claim 4**, Hijlkema discloses the fold lines are equally spaced apart (Fig. 6).

Regarding **claim 6**, Hijlkema discloses the at least one fold line comprises a crease in the balloon (Fig. 3 Item 22).

Claims 54 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyagawa et al. (U.S. 6,468,243).

Regarding **claim 54**, Miyagawa et al. discloses a method of treating a body lumen of a patient, the method comprising: providing a catheter having a balloon with at least one fold line formed in the wall of the balloon and extending helically along the outer surface of the balloon (Fig. 1 Item 1), inserting the catheter in its helically-folded state into the body lumen; advancing the catheter to a treatment site within the lumen; and inflating the balloon to engage a wall of the lumen to treat the lumen (Col 3 Lines 24-33).

Regarding **claim 55**, Miyagawa et al. discloses deflating the balloon so that the at least one fold collapses into the helically compressed state to disengage the wall of the lumen; and removing the catheter from the lumen (Col 3 Lines 30-33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3731

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hijlkema.

Hijlkema discloses the invention substantially as claimed as stated above.

Regarding **claim 2**, Hijlkema does not disclose the radially expandable balloon comprising two to five helical fold lines extending helically along at least a portion of the surface of the balloon. However, Hijlkema does disclose six helical fold lines (Fig. 6). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify Hijlkema to include two to five helical fold lines because Applicant has not disclosed that two to five helical fold lines provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Hijlkema's six fold lines because the reference gives the same reason for folding the balloon as the Applicant, for reducing the diameter of balloon for ease of entrance and removal from a patient's body.

Claims 5 and 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hijlkema in view of Trotta (U.S. 2002/0077606), Miyagawa et al. (U.S. 6,468,243), Wolvek et al. (U.S. 4,276,874), and Shiber (U.S. 2002/0151924).

Hijlkema discloses the invention substantially as claimed as stated above.

Regarding **claim 5**, Hijlkema does not disclose the at least one fold line comprises a groove in the balloon. Trotta teaches a groove in the balloon

Art Unit: 3731

(Paragraph 33) for enabling perfusion of blood past the balloon. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Trotta's groove. Such a modification enables perfusion of blood past the balloon.

Regarding **claim 7**, Hijlkema does not disclose the balloon being folded along the preformed fold lines to form lobes. Miyagawa et al. teaches the balloon being folded to form lobes (Fig. 1 Item 1) to reduce resistance upon entry and exit of a vessel. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Miyagawa et al.'s lobes. Such a modification would allow for entrance and exit of a vessel with reduced resistance.

Regarding **claim 8**, Hijlkema does not disclose the balloon being folded along the preformed fold lines to form flaps. Wolvek et al. teaches the balloon being folded to form flaps (Fig. 5 Item 64). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Wolvek et al.'s flaps. Such a modification would permit insertion and guiding of the catheter into the vessel.

Regarding **claim 9**, Hijlkema does not disclose a scoring structure adjacent to the fold lines. Shiber teaches a scoring structure adjacent to the fold lines (Fig. 10 and Paragraph 38). Therefore, it would have been obvious to a

Art Unit: 3731

person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Shiber's scoring structure adjacent to the fold lines. Such a modification harbors the scoring structure.

Regarding **claim 10**, Hijlkema does not disclose the scoring structure comprising at least one scoring element spirally circumscribing the balloon. The structure described above in the rejection for claim 9, which includes the combination of Hijlkema's balloon catheter and Shiber's scoring structure, would place Shiber's scoring structure adjacent to Hijlkema's helical folds. Shiber teaches a scoring element circumscribing the balloon (Fig. 11 Item 93 and Paragraph 41). The structure created by this combination would thus disclose a scoring element spirally circumscribing the balloon. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Shiber's scoring element. Such a modification provides an element for engaging an obstruction, in which the folds prior to inflation of the balloon harbor the element.

Regarding **claim 11**, Hijlkema does not disclose the scoring element continuously circumscribing the balloon. Shiber teaches the scoring element continuously circumscribing the balloon (Fig. 11 Item 93). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Shiber's scoring element. Such a modification allows the scoring element to be flexibly

Art Unit: 3731

bendable but still have a rigid cross section that will not cave-in when pushed into the surrounding obstruction material.

Regarding **claim 12**, Hijlkema does not disclose the scoring element comprising a plurality of segments. Shiber teaches the scoring element comprising a plurality of segments (Fig. 5 Item 19). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Shiber's scoring element. Such a modification would allow enhanced longitudinal flexibility.

Regarding **claim 13**, Hijlkema does not disclose the scoring element comprising a wire. Shiber teaches the scoring element comprising a wire (Fig. 8 Item 92 and Paragraph 41). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Shiber's scoring element. Such a modification would allow the scoring element to be wound into the spiral structure of the scoring element.

Regarding **claim 14**, Hijlkema does not disclose the scoring element being secured to an outer surface of the balloon. Shiber teaches the scoring element being secured to an outer surface of the balloon (Fig. 10 and Paragraph 39). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to

Art Unit: 3731

include Shiber's attached scoring element. Such a modification would enable the scoring structure to be radially pushed outward when the balloon is inflated to engage an obstruction.

Regarding **claim 15**, Hijkema discloses the invention substantially as claimed as stated above. Hijkema does not disclose at least one helical scoring structure located within the helical recess of the balloon, wherein the helical recess shields the scoring structure from exposure when the balloon is not expanded. Shiber teaches at least one helical scoring structure located within the recess of the balloon, wherein the recess shields the scoring structure from exposure when the balloon is not expanded (Fig. 10 and Paragraph 39).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijkema's balloon catheter to include Shiber's scoring structure adjacent to the fold lines. Such a modification harbors the scoring structure.

Regarding **claim 16**, Hijkema does not disclose the scoring structure comprising at least one scoring element spirally circumscribing the balloon. The structure described above in the rejection for claim 9, which includes the combination of Hijkema's balloon catheter and Shiber's scoring structure, would place Shiber's scoring structure adjacent to Hijkema's helical folds. Shiber teaches a scoring element circumscribing the balloon (Fig. 11 Item 93 and Paragraph 41). The structure created by this combination would thus disclose a

Art Unit: 3731

scoring element spirally circumscribing the balloon. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Shiber's scoring element. Such a modification provides an element for engaging an obstruction, in which the folds prior to inflation of the balloon harbor the element.

Regarding **claim 17**, Hijlkema does not disclose the scoring element continuously circumscribing the balloon. Shiber teaches the scoring element continuously circumscribing the balloon (Fig. 11 Item 93). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Shiber's scoring element. Such a modification allows the scoring element to be flexibly bendable but still have a rigid cross section that will not cave-in when pushed into the surrounding obstruction material.

Regarding **claim 18**, Hijlkema does not disclose the scoring element comprising a plurality of segments. Shiber teaches the scoring element comprising a plurality of segments (Fig. 5 Item 19). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Shiber's scoring element. Such a modification would allow enhanced longitudinal flexibility.

Art Unit: 3731

Regarding **claim 19**, Hijlkema does not disclose the scoring element comprising a wire. Shiber teaches the scoring element comprising a wire (Fig. 8 Item 92 and Paragraph 41). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Shiber's scoring element. Such a modification would allow the scoring element to be wound into the spiral structure of the scoring element.

Regarding **claim 20**, Hijlkema does not disclose the scoring element being secured to an outer surface of the balloon. Shiber teaches the scoring element being secured to an outer surface of the balloon (Fig. 10 and Paragraph 39). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Hijlkema's balloon catheter to include Shiber's attached scoring element. Such a modification would enable the scoring structure to be radially pushed outward when the balloon is inflated to engage an obstruction.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The

Art Unit: 3731

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

2/7/06